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EXAMINER

MARSCHER, ARDIN H

ART UNIT

PAPER NUMBER

1631

DATE MAILED: 01/23/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

# Office Action Summary

## Application No.

09/866,511

## Applicant(s)

PIERCE ET AL.

## Examiner

Ardin Marschel

## Art Unit

1631

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

## Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

## Status

- 1) ☒ Responsive to communication(s) filed on 14 October 2003.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

## Disposition of Claims

- 4) ☒ Claim(s) 1-15 and 20-27 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-15 and 20-27 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

## Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

## Priority under 35 U.S.C. §§ 119 and 120

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.
- 13) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application) since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.
- a) ☐ The translation of the foreign language provisional application has been received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121 since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.

## Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) 2 sheets
- 4) ☐ Interview Summary (PTO-413) Paper No(s). \_\_\_\_\_
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other:

### **DETAILED ACTION**

#### **CLAIM RENUMBERING**

The numbering of claims is not in accordance with 37 CFR 1.126 which requires the original numbering of the claims to be preserved throughout the prosecution. When claims are canceled, the remaining claims must not be renumbered. When new claims are presented, they must be numbered consecutively beginning with the number next following the highest numbered claims previously presented (whether entered or not).

Misnumbered claims 27 and 28 have been renumbered as claims 26 and 27, respectively. The dependency of claim now numbered 27 has been correspondingly changed to depend from claim now numbered 26.

#### **RESTRICTION ELECTION**

Applicant's election without traverse of Group I (now claims 1-15 and 20-27) in the Paper filed 10/14/03 is acknowledged.

#### **NEW MATTER**

Claims 26 and 27 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

Instant claim 1 directs the claimed method to being executed by a computer under control of a program. Added claims 26 and 27 are directed to making at least one protein as well as testing for stability and function. Consideration of the written support

which was pointed to by applicants as filed on pages 44-45 of the specification has failed to reveal any computer program control or execution by a computer of the protein making or testing as now set forth in instant claims 26 and 27. Therefore, these claims contain NEW MATTER regarding these limitations therein.

### **VAGUENESS AND INDEFINITENESS**

Claims 1-15 and 20-27 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 1, last line, indicates that a "Hybrid Exact Rotamer Optimization (HERO) step" is included in the analyzing of step (C) of the claim. This citation is confusingly interpreted in two inconsistent ways. One interpretation is that HERO as a method contains one step (singular) only. This conflicts also with the specification on page 7, lines 29-31, where three search paradigms comprise HERO which is a plurality of steps, at least being three searches, albeit run simultaneously as cited therein. It is thus unclear what is the HERO step as required in instant claim 1. Another interpretation of said phrase from claim 1 is that the analyzing step (C) of claim 1 only is required to utilize one step out of HERO. Thus, any step within the HERO algorithm of steps would be a step (C) analysis without utilizing all of the above noted three search steps in HERO. The specification as filed also cites a variety of HERO steps on pages 13-14, for example, none of which are cited as "the" HERO step as in the instant claims. Independent claim 20 also contains this unclear "a HERO computation step" limitation. Clarification via clearer claim wording is requested. Claims which are directly or

indirectly dependent from either of claims 1 or 20 are also rejected hereinunder as containing the above unclarity due to their dependence.

### **NON-STATUTORY SUBJECT MATTER**

35 U.S.C. 101 reads as follows:

Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

Claims 1-8, 10-12, 15, and 20-25 are rejected under 35 U.S.C. 101 because the claimed invention is directed to non-statutory subject matter.

Consideration of the "Computer-Related Inventions" section of the MPEP at section 2106, Part IV, subpart B, has revealed that the instant claims are directed to non-statutory subject matter without requiring performance of a result outside of a computer. Thus, the manipulation of data or conversion of data, in this case protein design calculations is the claimed subject matter without any physical transformation outside of the computer.

### **PRIOR ART**

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 1-15 and 20-27 are rejected under 35 U.S.C. 102(e)(2) as being clearly anticipated by Mayo et al. (P/N 6,188,965).

In the abstract, Mayo et al. summarize the subject matter therein disclosed as being directed to protein design and optimization as is also the instantly claimed subject matter. The computer-assisted design methodology as also instantly claimed is disclosed in column 5, lines 43-54. In column 4, lines 41, a known protein structure called the template including the backbone structure is defined with variable residues or possible amino acid residues as also required in instant claim 1, step (A). The potential rotamers with at least different amino acid side chains options are established as disclosed in column 4-5, bridging paragraph, as also required in instant claim 1, step (B). This is further detailed in the reference in column 7, lines 15-59. Scoring functions as cited also in instant claims 3 etc. as cited in the reference in column 5, lines 1-8. Rotamer calculations directed to sets of potential rotamers are analyzed in column 5, lines 1-37, including global optimum energy for a single sequence as also required in instant claim 2. In this section DEE is utilized as well as Monte Carlo searching (also instant claims 11 and 12) which are each steps of the instantly summarized HERO calculation as set forth in the instant specification on pages 13-14, for example. Since these are each a HERO step, the disclosure of these steps anticipates step (C) of instant claim 1. Column 5, lines 1-8, cite scoring functions as in instant claims 4-7 directed to van der Waals potential etc. Scaling factor practice to compensate for overcounting regarding exposed vs. buried area which determines salvation scoring is cited in column 4, lines 20-23, and in column 12, line 66, through column 13, line 3, as also required in instant claim 8. Testing is disclosed in the reference in column 5, lines 38-42, as also required in instant claims 9 and 13. Ranking as in instant claim 10 is cited in

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the reference in column 5, lines 24-37. In the examples of Mayo et al., in particular in column 33, line 63, through column 34, line 44, the additional testing to analyze correspondence between potential energy test results and theoretical potential energy data is set forth as also required in instant claim 14. The variation of supersecondary structure parameter value as in instant claim 15 is set forth in the reference in column 65, lines 38-64. Corresponding limitations are present in instant claims 20-25 as summarized above. The protein making and testing for function and stability as in added claims 26 and 27 are also set forth in the reference in column 25, line 63, through column 26, line 36.

#### **INFORMATION DISCLOSURE STATEMENT**

Enclosed is a PTO Form 1449 with the references lined through as not having been considered due to a lack of finding copies of said references as required. It is also noted that the IDS filing was indicated as a "Supplemental" IDS which is indicative that it supplements a previously filed IDS. No such previously filed IDS has been found as having been submitted.

No claim is allowed.

Papers related to this application may be submitted to Technical Center 1600 by facsimile transmission. Papers should be faxed to Technical Center 1600 via the Central PTO Fax Center. The faxing of such papers must conform with the notices published in the Official Gazette, 1096 OG 30 (November 15, 1988), 1156 OG 61 (November 16, 1993), and 1157 OG 94 (December 28, 1993)(See 37 CFR § 1.6(d)). The Central PTO Fax Center number is (703) 872-9306.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Ardin Marschel, Ph.D., whose telephone number is (571)272-0718. The examiner can normally be reached on Monday-Friday from 8 A.M. to 4 P.M.

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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Woodward, Ph.D., can be reached on (571)272-0722.

Any inquiry of a general nature or relating to the status of this application should be directed to Legal Instrument Examiner, Tina Plunkett, whose telephone number is (571)272-0549 or to the Technical Center receptionist whose telephone number is (703) 308-0196.

January 20, 2004

  
ARDIN H. MARSCHEL  
PRIMARY EXAMINER